Initial REMS Approval: 11/2008
Most Recent Modification: 03/2011

NDA 021911 and NDA 201367
BANZEL® (rufinamide) Tablets and Oral Suspension

Antiepileptic Drug

Eisai Inc.

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to inform patients of the serious risks associated with BANZEL, including the increased risk of suicidal thoughts and behavior.

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each Banzel prescription in accordance with 21 CFR 208.24.

B. Timetable for Submission of Assessments

Eisai Inc. will submit REMS Assessments to the FDA at a minimum, by 18 months, by 3 years and in the 7th year from the initial approval of the REMS (November 14, 2008) according to the schedule below:

1st FDAAA assessment: May 14, 2010 (18 months from approval)
2nd FDAAA assessment: November 14, 2011 (3 years from approval)
3rd FDAAA assessment: November 14, 2015 (7 years from approval)

To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Eisai Inc. will submit each assessment so that it will be received by the FDA on or before the due date.

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/s/

RUSSELL G KATZ
03/03/2011